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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/482,688 01/13/00 GARDINER

P 23925-4

HM22/1204

EXAMINER

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ART UNIT	PAPER NUMBER
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1616

DATE MAILED:

12/04/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trad marks**

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/482,688	GARDINER ET AL.
	Examiner	Art Unit
	Frank I Choi	1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 18 September 2000.
- 2a) This action is **FINAL**.                                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-61 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-61 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - a) All b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

**Attachment(s)**

15) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____	20) <input type="checkbox"/> Other: _____

## **DETAILED ACTION**

### ***Response to Amendment***

The amendment filed 9/18/00 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: Claim 60, "from 13 mg to 11,000mg" and Claim 61 "from 275mg to 5500". The disclosure does not appear to have these ranges and Applicant does not appear to have adequately explained how said ranges were derived from the Specification as originally filed. Examiner has duly considered Applicants citation to Pg. 7, lines 2-15 but it is not clear how the claimed ranges are derived therefrom.

Applicant is required to cancel the new matter in the reply to this Office Action.

### ***Claim Objections***

Claims 3, 5-7, 9, 10, 13, 15-18, 20-24, 26, 27, 29-33, 35, 36, 38-42, 44, 45, 47-51, 53-57, 60, 61 objected to because of the following informalities: Dependent claims should begin with "The" except in the case where a method claim depends on a composition claim. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4, 8, 14, 25, 28, 34, 37, 43, 46, 58 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specified substances

(Specification, pg. 5, lines 17-33, pg. 6, lines 1-4, does not reasonably provide enablement for all substances which might conceivably fall within the scope of the claimed invention. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. Applicant claims any substance which could cause an increase in nitric oxide production or mimics and/or enhances insulin activity, however, only a small list of substances is disclosed. Applicant does not appear to disclose how a skilled artisan would be able to determine whether a given substance increases nitric oxide production or mimics and/or enhances insulin activity. As such, it appears that a skilled artisan would be required to do undue experimentation in order to make and/or use the invention commensurate in scope with the claims.

Claims 60, 61 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. It appears that the ranges are not disclosed within the Specification, however, Applicant does not appear to have adequately explained how the range of 13 – 11000 mg and 275-5500 mg was arrived at and how said ranges do not constitute new matter. See above discussion.

***Claim Rejections - 35 USC § 102/103***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 8, 9 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Schneider et al. (U.S. Pat. 5,902,899).

Schneider et al. expressly discloses a composition comprising arginine and amino acids (Column 7, lines 15-68, Column 2, Column 9, Claims 1-17) falling within the scope of applicant's claims.

Alternatively, at the very least the claimed invention is rendered obvious within the meaning of 35 USC 103, because the prior art discloses products and uses that contain the same exact ingredients/components as that of the claimed invention. See *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

Claims 1, 8, 9, 13-17, 58-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schneider et al. (U.S. Pat. 5,902,899).

Schneider et al. teaches a composition containing arginine and amino acids, such as whey protein, which can be in powdered form, that provides a source of nitrogen/nitric oxide (Column 2, lines 26-29, Column 4, lines 16-17, Column 7, lines 15-68, Column 2, Column 9, Claims 1-17)

The difference between the cited reference and the claimed invention is that the cited reference does not expressly disclose a composition comprising in combination arginine and whey protein. However, the prior art amply suggests the same as it is known in the art that whey protein is a suitable source of amino acids. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that whey derived proteins would provide a suitable source of nitrogen.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been taught by the teachings of the cited reference.

Claims 1, 2, 8, 13-17, 58, 59 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Uiterwaal et al. (U.S. Pat. 4,710,387)

Uiterwaal et al. expressly discloses a composition comprising folic acid and whey protein falling within the scope of applicant's claims (Column 5, lines 48-68, Column 6, Column 7, lines 1-49).

Alternatively, at the very least the claimed invention is rendered obvious within the meaning of 35 USC 103, because the prior art discloses products and uses that contain the same exact ingredients/components as that of the claimed invention. See *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980). See also *In re May*, 197 USPQ 601, 607 (CCPA 1978).

Claims 1-4, 8, 13-18, 25-28, 34-37, 43-46, 58 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Portman.

Portman expressly discloses a composition which is used to rebuild muscle comprising arginine, whey protein and ginseng falling within the scope of applicant's claims (Column 18, lines 5-38, Claims 1-77).

Alternatively, at the very least the claimed invention is rendered obvious within the meaning of 35 USC 103, because the prior art discloses products and uses that contain the same exact ingredients/components as that of the claimed invention. See *In re May*, 197 USPQ 601, 607 (CCPA 1978). See also *Ex parte Novitski*, 26 USPQ2d 1389, 1390-91 (Bd Pat. App. & Inter. 1993).

Claims 1-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Portman in view of Doi et al., Kim et al., Droke, Larner et al. and Jableck et al.

Portman teaches composition which is used to rebuild muscle comprising arginine, whey protein and ginseng (Column 18, lines 5-38, Claims 1-77). It is taught that protein sources including whey are important for release of insulin and repair of muscle damage during and after exercise (Column 11, lines 39-50). It is taught that herbal compounds such as ginseng enhance immune system, reduce muscle stress and decrease heart rate during exercise (Column 13, lines 27-34). It is taught that protein and arginine are effective in stimulating insulin and that the stimulation of insulin is important in the rebuilding of muscle (Column 17, lines 25-54, Column 18, lines 5-39).

Doi et al. teaches that administration of glucomannan reduces blood glucose levels (Abstract).

Kim et al. teaches that saponins derived from ginseng promote release of nitric oxide in the body (Abstract).

Droge teaches that administration N-acetyl cysteine in combination with insulin-like growth factor, or a nutrient such as amino acid increases muscle mass (Column 1, lines 5-9, 39-45, 55-59).

Lerner et al. teaches that d-chiro-inositol, which is related to myoinositol, is effective in regulating insulin (Column 1, lines 18-65, Column 2, lines 14-43).

Jablecki et al. teaches that the incorporation of inositol into phosphatidylinositol in muscles is related to increased muscle activity sufficient to produce compensatory hypertrophy (Abstract).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose using N-acetyl cysteine, glucomannan or inositol compounds to increase muscle mass. However, the prior art amply suggests the same as it is known that the activity of insulin is important in converting glucose into glycogen which is utilized by muscle cells for growth, proteins increase the activity of insulin, that glucomannan appears to have similar activity to insulin in lowering blood glucose levels, N-acetyl cysteine combined with insulin-like growth factors and amino acids is effective in increasing muscle growth and inositol compounds are effective in regulating insulin and are implicated in mechanisms from muscle hypertrophy due to exercise. Further, Examiner takes official notice that administration of arginine will result in increased nitric oxide/nitrogen in the body (See Schneider et al. above). As such, it would have been well within the skill of an ordinary skill in the art to have been motivated to modify the prior art as above with the expectation that the composition would be effective in increasing muscle mass, mimicing and/or enhancing the effect of insulin and increasing nitric oxide/nitrogen in the body.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

***Conclusion***

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machines are (703) 308-4556 or (703) 305-3592.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (703) 308-0067.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. José Dees, can be reached on (703) 308-4628.

FIC

December 1, 2000



JOHN PAK  
PRIMARY EXAMINER  
GROUP 1600

